DEC - 5 2000

510(k) SUMMARY K002105
as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Systems, Inc.
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Danvers, MA 01923
Tel: (978) 907-7500
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Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: July 10, 2000

2. Trade Name, Common Name and Classification Name:
   A. Trade Name:
   INFINITY SC 6002XL Enhanced with ST Segment Analysis

   B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Cardiac Monitor	74DRT	II	21 CFR 870.2300
Pulse Rate Monitor	74BWS	II	21 CFR 870.2300
Pulse Oximeter	74DQA	II	21 CFR 870.2700
Breathing Frequency Monitor	73BZQ	II	21 CFR 868.2375
Clinical Electronic Thermometer	80BWX	II	21 CFR 880.2910
Indwelling Blood Pressure Monitor	74CAA	II	21 CFR 870.1110
Noninvasive Blood Pressure Monitor	74DXN	II	21 CFR 870.1130
Heart Rate Monitor, Neonatal	74FLO	II	21 CFR 870.2300
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 868.2375
Monitor Blood Pressure, Neonatal, Invasive	74FLP	II	21 CFR 870.1110
Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	73CCK	II	21 CFR 868.1400
ST Segment Monitor with Alarm	74 MLD	III	21 CFR 870.1025
Arrhythmia Detector & Alarm System	74DSI	III	21 CFR 870.1025
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	III	21 CFR 870.1025

3. Predicate Device Identification:
   INFINITY SC 6002XL, 510(k) K993974
   SC 9000/SC 9015 Enhanced with ST Segment Analysis, 510(k) K970920

4. Device Description:

The INFINITY SC 6002XL (K993974) has been enhanced with ST Segment Analysis. The ST Segment algorithm is a locked option of the SC 6002XL software version VF0. This locked software option determines the ST Segment of the ECG signal and computes the deviation of this ST Segment from the iso-electric point (baseline). This is the same ST algorithm that is used and which was submitted with Siemens INFINITY SC 9000/SC 9015 Bedside Monitoring System Enhanced with ST Segment Analysis, K970920. The hardware of the INFINITY SC 6002XL remains the same as that submitted in 510(k) K993974.

The ST Segment Analysis is not active when the INFINITY SC 6002XL is in the neonatal mode.

5. Intended Use:

The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea, end-tidal carbon dioxide, and ST Segment Analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to Siemens R50 recorders, either directly or via the INFINITY network.

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6. Table of Device Similarities and differences to predicate device

	Predicate Device SC 9000 / SC 9015 with ST Segment Analysis	Applicant INFINITY SC 6002XL with ST Segment Analysis	Explanation of the modified version
Manufacturer	Siemens Medical Systems	Same	
510(k) Number	K970920	To be assigned	
Intended Use	The intended use of the SC 9000 / SC 9015 Bedside Monitoring System is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, temperature, arrhythmia, cardiac output, arterial oxygen saturation, pulse rate, end-tidal carbon dioxide, (central) apnea, and ST segment analysis. The device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to the Siemens SIRENET or INFINITY network.	The intended use of this device is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, central apnea, end-tidal carbon dioxide, and ST Segment Analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to Siemens R50 recorders, either directly or via the INFINITY network.	The INFINITY SC 6002XL does not monitor cardiac output.
Intended Population	Adult/Pediatric/Neonatal	Same	Arrhythmia and ST segment analysis ar not intended for neonatal use.
Intended Environment	An environment where patient care is provided by healthcare professionals	Same	
Leads processed	Any three of I, II, III, aVR, aVL, aVF, V, V+, V1 – V6	Any two of I, II, III, aVR, aVL, aVF, V, V+	The SC 6002XL processes two leads
ISO point adjustment range	Complex start to fiducial point	Same	
ST measurement point adjustment range	Fiducial point to complex end	Same	
Alarms	Yes	Same	

7. Assessment of non-clinical performance data for equivalence: Section U

8. Assessment of clinical performance data for equivalence:
The ST Segment Analysis of the INFINITY SC 6002XL monitor is equivalent to the ST Segment Analysis of the predicate device.

9. Biocompatability:
Not applicable

10. Sterilization:
Not applicable

11. Standards and Guidance:
The INFINITY SC 6002XL with ST Segment Analysis complies with:

FDA Guidance for Industry, "Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement)"

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

Ms. Penelope H. Greco
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K002105
INFINITY SC 6002XL Enhanced with ST Segment Analysis
Regulatory Class: III (three)
Product Code: 74 MLD, MHX, MSX
Dated: July 10, 2000
Received: July 12, 2000

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002105

Device Name: INFINITY SC 6002XL Portable Patient Monitor

Indications for Use:

This device is capable of monitoring:

- Heart Rate
- Respiration Rate
- Invasive Pressure
- Non-Invasive Pressure
- Arrhythmia
- Temperature
- Arterial oxygen saturation
- Pulse rate
- (central) apnea
- end-tidal CO2
- ST Segment Analysis

This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to Siemens R50 recorders, either directly or via the INFINITY network.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of Arrhythmia and ST Segment Analysis which are not intended for the neonatal population.*

MRI Compatibility Statement:
The Siemens INFINITY SC 6002XL is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Division of Cardiovascular & Respiratory Devices
510(k) Number K002105